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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/709,585	11/13/2000	Aaron I. Vinik	05126.00002	4730

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BANNER & WITCOFF  
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WASHINGTON, DC 20001

EXAMINER

CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/709,585	<b>Applicant(s)</b> VINIK ET AL.	
	<b>Examiner</b> Karen Cochrane Carlson, Ph.D.	<b>Art Unit</b> 1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-12,14-16 and 19-36 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3-12,14,16,19-28,30-32 and 34 is/are allowed.
- 6) ☒ Claim(s) 15,29,33,35 and 36 is/are rejected.
- 7) ☒ Claim(s) 30 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>all</u> . | 6) <input type="checkbox"/> Other: _____  |

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This Office Action is in response to the paper filed December 12, 2003. Claims 2, 13, 17, and 18 have been canceled. Claims 1, 3-12, 14-16, and 19-36 are currently pending and are under examination.

Priority date is February 22, 1995.

The Examiner thanks Applications for properly adding these new claims 29-36 in response to the previous Office Action.

The Examiner appreciates Applicants thoughtfulness in providing page 2 of the reissue IDS. An initialed copy of this page 2 is found in the electronic files, but Pittenger et al. was not initialed. Another initialed copy of page 2 is attached to this Office Action, as well as copies of the previously initialed 1449s to insure that Applicants have a copy of all 1449s.

#### **Withdrawal of Rejections**

The bar by recapture of reissue Claims 29, 30, 33, and 34 is withdrawn.

The rejection of Claims 1, 3, 7, 8, 12, 14, 17, 18, 21, 25, 26, 27, and 28 under 35 U.S.C. 102(a) as being anticipated by Watanabe et al. (April, 1994; PNAS 91:3589-3592) is withdrawn.

The rejection of Claims 1, 3, 6, 7, 8, 11, 12, 14, 17, 18, 21, 22, 25, 26, 27, and 28 under 35 U.S.C. 102(b) as being anticipated by Pettenger et al. 1992, is withdrawn.

#### **Maintenance of Rejections**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 15, it is not clear if it is the "at least 15 amino acids" of INGAP or the second polypeptide that provides the beta cell stimulatory activity.

Applicants state that Claim 15 has been amended to specify that the fusion protein is capable of stimulating beta cell regeneration. The question still remains, is it the "at least 15 amino acids" of INGAP or the second polypeptide that provides the beta cell stimulatory activity?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are drawn to protein which is not defined by structure and function. Without structure correlated with function, one cannot know which proteins are in Applicants possession. Therefore, the specification lacks written description of the claimed invention.

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Applicants urge that no legal basis has been provided to require that the claimed polypeptide be defined by structure and by function. The statute was cited – see above – and Applicants are referred to the Written Description Guidelines, Example 14.

### **New Rejections and Objections**

Claims 35 and 36 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 31 and 32 (allowed herein). When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 35 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 35, the polypeptide is stated to "consist" of a portion of INGAP of "at least 15 consecutive amino acids". The term "consist" is closed language, while "at least 15 consecutive amino acids" is open language. Thus, the limitations of the claim is indefinite.

Claims 30 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 15, 29, 33, 35 and 36 are rejected.

Claims 1, 3-12, 14, 16, 19-28, 30-32, and 34 are allowed.

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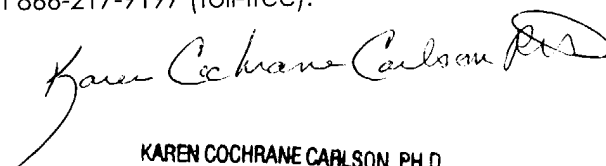
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER